

REMARKS

By this amendment, Applicants amend claims 358, 362-364, 372, 375-377, and cancel claims 371 and 385. Claims 1-357 have previously been canceled. Accordingly claims 358-365, 367-370, 372-378, and 380-384 are pending.

35 U.S.C. §112, Second Paragraph, Rejection

The Office rejected claims 358-365, 367-378, and 380-385 under 35 U.S.C. §112 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants amend herein claims 358, 362-364, 372, and 375-377, and cancel claims 371 and 385, and respectfully request withdrawal of the §112 rejection. The claims as amended or previously presented, address the Examiner's concerns and meet the statutory requirements of §112, as shown below.

Specifically, the Office Action, at page 7, asserted that claims 358 and 372 were unclear because the location of the first sample is not specified. Applicants amend claims 358 and 372 to recite "inserting a first sample into the stainer." The Office Action, at page 7, asserted that claims 362 and 372 were unclear as to the relative location of the recited database. Applicants amend claims 362 and 372 to recite "a server including a centralized database." The Office Action, at page 7, asserted that claims 363 and 375 were unclear as to what database the recited operations pertain to. Applicants amend claims 363 and 375 for clarification. The Office Action, at page 7, asserted that the recitation of "the database" in claim 364 lacked antecedent basis. Applicants amend claim 364 for clarification. The Office Action, at page 8, asserted that claims 364 and 377 were unclear for various reasons. Applicants amend claims 364

and 377 to clarify the manner in which diagnostic tests are run. The Office Action, at page 9, asserted that the location of the second stainer in claim 376 was unclear. Applicants amend claim 376 to recite "providing a second stainer to be included in the stainer network."

The Office Action, at page 8, also asserted that claims 365 and 378 were unclear as to what is meant by the claim language "actively exercising components," stating that "it is unclear what components are exercised." The Office Action, at page 8, then asserts with respect to claims 368 and 382, that "an operator can perform these steps (operations) by observing with one's own eyes, mentally." Applicants respectfully disagree with regards to each of these rejections. Each of these claims are clear on their face and no further clarification would be necessary to one of skill in the art. For example, Claims 365 and 378 recite that the "components on the stainer" are exercised. There is no reason to spell out exactly which components are exercised as one of skill in the art would clearly understand which of the components on the stainer should be exercised. While claims 368 and 382 specifically recite "automatic diagnostic operations," which cannot be carried out mentally. Applicants respectfully request that all of these rejections be withdrawn in view of the amendments and arguments provided herein.

35 U.S.C. §112, First Paragraph, Rejection

The Office rejected claims 358-365, 367-378, and 379-385 under 35 U.S.C. §112 as allegedly failing to comply with the written description requirement. Applicants amend claims 358, 362-364, 372, 375-377 , and, as discussed below, provide

exemplary support for each of the pending claims. Applicants therefore respectfully request the withdrawal of the 35 U.S.C. §112, first paragraph, rejection.

The M.P.E.P. provides, at §2163 I.B, that “there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure,” and that “[t]he fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.” See, e.g., *Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117. There is no requirement that claim language mirror the disclosure; the written description requirement of §112 requires only that the disclosure demonstrate that applicant was in possession of the invention as claimed. The following provides exemplary support for the pending claims and is not meant in any way to limit the scope of the claims to the examples provided.

With respect to claim 358, Applicants demonstrate support as follows: A robotic arm coupled to the stainer is illustrated in Fig. 1 (item 120), and described, e.g., at page 9, lines 27-30. Establishing a network connection between a computer and a stainer in the stainer network is illustrated, e.g., in Fig. 8. Sending requests from the computer to the stainer over the network is described, e.g., at page 16, lines 1-5. Processing a first sample with the stainer using the requests received from the first computer, wherein said processing comprises dispensing reagents to the sample with the robotic arm is described, e.g., at page 16, lines 1-5, and page 32, lines 10-12. Inserting a first sample into the stainer is described, e.g., at page 4, lines 32-35. Inserting a second sample into the stainer and optionally at least one reagent into the stainer during the processing of

the first sample without interrupting the dispensing of reagents onto the first sample with the robotic arm is supported as follows, for example: Page 4, lines 32-35, describes that samples may be inserted or removed from the system during processing protocol steps. Page 32, lines 10-12, describes the dispensing of reagents as a process step. Page 24, lines 1-23 describe the insertion and removal of modules and drawers containing slides and reagents into the stainer during continuous, i.e. uninterrupted, processing, which includes, *inter alia* reagent dispensing.

With respect to claim 359, a computer functioning as a server and a stainer functioning as a client are illustrated, *e.g.*, in Fig. 7.

With respect to claims 360, and 374, a server including a centralized database including configuration information for the stainer is supported as follows: Page 27, lines 17-32, describe data sharing between sample processing systems (*e.g.*, stainers) and the system manager (*e.g.*, a server). Shared data may include configuration information including at least reagents, reagent type, slides, and protocols. A person of ordinary skill in the art would recognize that the shared configuration information stored in a server is stored in the database, the maintenance of which is described in the same paragraph.

With respect to claim 361, a stainer connected to a laboratory information system is illustrated, *e.g.*, in Fig. 9.

With respect to claim 362, the specification supports the claim language as follows: Network communication involving the sending of requests is described, *e.g.*, at page 16, lines 1-5. A server including a centralized database comprising information about the stainer, wherein the information includes status information on stainers,

slides, consumables, and treatment protocols of the stainer, is described, *e.g.*, at page 27, lines 17-32, as previously described with respect to claims 360 and 374.

With respect to claims 363 and 375, database maintenance operations including information purging, information compaction, and database information back-up operations are described, *e.g.*, at page 27, lines 17-32.

With respect to claim 364 and 377, support for the claim language may be found as follows: Network communication involving the sending of requests is described, *e.g.*, at page 16, lines 1-5. Controlling a sample processing system (*e.g.*, a stainer) with a computer is described, *e.g.*, at page 27, lines 20-22. Performing diagnostic tests on a system (*e.g.*, a stainer), is described, *e.g.*, at page 27, lines 29-32. Storage and retrieval of shared data, including system diagnostics, are explained, *e.g.*, at page 27, lines 17-32. User interaction with the network, *i.e.* for the provision of diagnostic information, is described at page 27, lines 34-35.

With respect to claims 365 and 378, actively exercising components of a stainer as a diagnostic test is described, *e.g.*, at page 27, lines 30-31. The specification, for example in Figs. 1, 2, 3, and 6, and at page 8, line 13 through page 10, line 10, contains ample description of components which a stainer may comprise. Claims 365 and 378 are not limited to the active exercise of specific components, as the Office Action suggests, but encompass the active exercise of any components of the claimed stainer.

With respect to claims 367 and 380, electronically notifying an operator about the results of diagnostic tests is supported, *e.g.*, at page 22, lines 33-35.

With respect to claims 368 and 382, the instant specification supports these claims as follows. Page 26, lines 31-33, describe how each sample processing system

(e.g., stainer) may be individually controlled. Page 27, lines 4-7, in the same paragraph as the above, describe automatic system diagnostic operations. A person of ordinary skill in the art would recognize that individualized control of multiple stainers permits the operation of a stainer to continue unaffected by diagnostics being performed on another stainer.

With respect to claims 369 and 383, page 27, lines 33-35, describes communication between a sample processing system (e.g., a stainer) and a system manager (e.g., a computer) to “allow identification, tracking, and status of sample batches, reagents, and other agents and components of the sample processing system.”

With respect to claims 370 and 384, providing a real time estimate of a completion time of a sample being processed by a stainer is described, e.g., at page 19, lines 22-24.

With respect to claim 372, all of the claim elements have previously been discussed, with respect to claims 358, 361, and 362.

With respect to claim 373, the stainer network further including a server and a plurality of stainers including the stainer, and wherein the stainer is a client of the server is illustrated, e.g., in Fig. 8.

With respect to claim 376, the claim elements are described in the specification as follows. Providing a second stainer to be included in the stainer network is illustrated, e.g., at Fig. 8. Checking by the computer for operational readiness in a stainer is disclosed, e.g., at page 28, lines 9-13 and Fig. 10. Sending requests to a second stainer when a first stainer is not ready is supported, e.g., by page 16, line 33

through page 17, line 15, describing the automated construction of an automatic processing routine based on various system factors.

With respect to claim 381, controlling the stainer from a remote location is described, e.g., at page 16, lines 8-12.

As demonstrated, all of the elements of the pending claims are supported by the as-filed specification in such a way as to convey with reasonable clarity to one of ordinary skill in the art that Applicants were in possession of the invention as claimed at the time of filing.

35 U.S.C. §102(e) Rejections

The claims are patentable over Feingold '201 because Feingold '201 is not a proper 102(e) reference.

Applicants respectfully traverse the 35 U.S.C. §102(e) and (a) rejection of claims 358-365 over Feingold et al. (U.S. 7,603,201, "Feingold '201"). The Office Action asserts that Feingold '201 is a 35 U.S.C. §102(e) reference because of an earlier effective filing date. Applicants respectfully disagree. Feingold '201 claims priority as a continuation or continuation-in-part to various earlier filings. While it is unclear to which filing the Office Action is referring to as establishing the effective U.S. filing date of Feingold '201 for §102(e) purposes, the earliest filing to which Feingold '201 claims priority is U.S. Provisional Application No. 60/435,601, (the '601 application) filed on December 20, 2002. See Feingold '201, col. 1, lines 22-23. The instant application is a U.S. National Stage of International Application No. PCT/US2003/041022, filed December 22, 2003, which claims the benefit under 35 U.S.C. §119(e) of the same '601

application, filed on December 20, 2002. See Preliminary Amendment filed on June 16, 2005. Thus, assuming the Office is relying on the disclosure of the '601 application as an effective filing date providing a prior art disclosure, the instant claims would also be entitled to priority of the '601 application for the same reasons. The cited reference, therefore, is not an appropriate §102(e) reference, as it does not have an earlier effective filing date.

Claims 358-360, 369, 372, 381, and 383 are patentable over Kalra at least because Kalra fails to disclose or suggest all of the claimed elements.

Applicants respectfully traverse the 35 U.S.C. §102(b) rejection of claims 358-360, 369, 372, 381, and 383 over Kalra et al. (U.S. 6,495,106, "Kalra"). The Office Action asserts that Kalra discloses all of the elements of the rejected claims. Applicants respectfully disagree. Kalra does not disclose or suggest all of the elements of amended independent claims 358 and 372, including at least "inserting a second sample into the stainer and optionally at least one reagent into the stainer during the processing of the first sample without interrupting the dispensing of reagents onto the first sample with the robotic arm."

The instant Office Action asserts that Kalra discloses all of the elements of independent claims 358 and 372, including "batch processing [such] that the apparatus can process trays of slides in a manner which completes the prescribed processing on a single tray 190, and then signal[s] the user to remove the tray and replace it with a fresh tray, without interrupting the processing of the remaining trays." Office Action, at page 13. This is different from independent claims 358 and 372 that recite "inserting a second sample into the stainer and optionally at least one reagent into the stainer

during the processing of the first sample **without interrupting the dispensing of reagents onto the first sample with the robotic arm.**" Kalra does not disclose this feature of independent claims 358 and 372. Instead, when read in the context of the application Kalra discloses that the operation of the instrument pauses (i.e., returns to the home position and waits) after completion of a first tray and before processing of a second tray. Only then can the first tray be replaced before processing of the second tray begins. Thus, by pausing, the dispensing of the reagents in the stainer of Kalra is interrupted as the term is used in claims 358 and 372 of the instant application. This is very different from inserting a sample without interrupting dispensing of reagents as claimed. In fact, as described below, Kalra discloses a structure which does not permit the feature of independent claims 358 and 372.

Specifically, as illustrated in FIG. 1, Kalra discloses an apparatus in which a movable arm 30 is arranged above an array of slide trays 190. The slide trays 190 are designed to be removed from above. Due to this arrangement, removal of the slide trays crosses the plane of the moveable arm. Thus, in order to prevent interference between an operator and the movable arm, Kalra discloses at col. 9, line 66 to col. 10, line 3, that "moveable arm 30 is shown in its home position, to which the arm returns when not in use. The home position is desirably selected to minimize interference with other operations, such as the insertion of microscope slides." Additionally, Kalra, at col. 17, lines 19-21 discloses "that the apparatus can process trays of slides in a manner which completes the prescribed processing on a single tray 190, and then signal the user to remove the tray and replace it with a fresh tray." Thus, Kalra discloses an apparatus that signals the user to remove a slide tray 190 and positions the moveable

arm 30 in a safe "home position," during this operation. In other words, the apparatus pauses or interrupts processing when a slide tray is removed or added.

In contrast, independent claims 358 and 372 recite "inserting a second sample into the stainer and optionally at least one reagent into the stainer during the processing of the first sample without interrupting the dispensing of reagents onto the first sample with the robotic arm." Kalra does not disclose that a second sample and optionally at least one reagent may be inserted without interrupting the dispensing of reagents from the reagent tip head 40 of the Z head 70, located on the moveable arm 30. Kalra, in fact, discloses that the moveable arm 30 is returned to a "home position", when "not in use," during the insertion of microscope slides.

Therefore, because Kalra does not disclose all of the elements of amended independent claims 358 and 372, the §102(b) rejection is not supported. Claims 357, 360, 369, 381, and 383 depend from claims 358 and 372 and are similarly not anticipated for at least the same reasons.

35 U.S.C. §103(a) rejection

Claims 361-365, 367-368, 370, 373-378, 380, 382, and 384 are patentable over Kalra in view of Lemme at least because the cited references do not disclose all of the elements of the claims.

Applicants respectfully traverse the 35 U.S.C. §103(a) rejection of claims 361-365, 367-368, 370, 373-378, 380, 382, and 384 over Kalra in view of Lemme et al. (U.S. 2002/0110494 A1, "Lemme"). The Office Action cites Lemme as purportedly disclosing multiple stainers in a network. Lemme, however, does not disclose or suggest the above-discussed features of independent claims 358 and 372 missing from Kalra.

Claims 361-365, 367-368, 370, 373-378, 380, 382, and 384 depend from claims 358 and 372 and incorporate all of the features thereof. Therefore, the cited references, taken alone or in combination, do not disclose all of the features of claims 361-365, 367-368, 370, 373-378, 380, 382, and 384, and no prima facie case of obviousness is established.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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